K062152

510(k) Summary for the
Dimension® Clinical Chemistry System
Dimension Vista™ System
Creatine Kinase MB Isoenzyme Verifier
(CKMB Verifier – DC27)

AUG 16 2006

A. 510(k) Number:

B. Analyte: Creatine Kinase MB Isoenzyme (CKMB)

C. Type of Test: Calibrator Material

D. Applicant: Dade Behring Inc., P.O. Box 6101, Newark, DE 19714-6101
Victor M. Carrio, Regulatory Affairs and Compliance Manager
Office: (302) 631-0376 Fax: (302) 631-6299

E. Proprietary and Established Names:

Dimension® Creatine Kinase MB Isoenzyme Verifier
(CKMB Verifier – DC27)

F. Regulatory Information:

1. Regulation section: 21 CFR § 862-1150 – Calibrator
2. Classification: Class II
3. Product Code: JIT – Calibrator, Secondary
4. Panel: Clinical Chemistry

G. Intended Use: The Creatine Kinase MB Isoenzyme Verifier is an *in vitro* diagnostic product for verification of the Creatine Kinase MB Isoenzyme (CKMB) method on the Dimension® clinical chemistry system and Dimension Vista™ System.

H. Device Description:

CKMB Verifier is a lyophilized human serum base product. Level 1 contains no CKMB, Levels 2 and 3 contain CKMB from a simian heart source.
The kit consists of six vials, two vials per level. The volume per vial is 1.0 mL.

I. Substantial Equivalence Information:

The intended use of the Dimension® CKMB Verifier has been expanded beyond the intended use stated for this product in a previous 510(k) submission (see K863840). All features of the product remain the same as described in K863840 except that now the product will be used for verification of the Creatine Kinase MB Isoenzyme (CKMB) method on the Dimension® clinical chemistry system **and Dimension Vista™ System**.

Item	Dimension® CKMB Verifier
Intended Use	The Creatine Kinase MB Isoenzyme Verifier is an *in vitro* diagnostic product for verification of the Creatine Kinase MB Isoenzyme (CKMB) method on the Dimension® clinical chemistry system **and Dimension Vista™ System.**
Analytes	Creatine Kinase MB Isoenzyme
Form	Lyophilized
Traceability	Dimension® clinical chemistry system values.
Matrix	Human serum based product containing CKMB from simian heart source.
Levels	Three levels.

J. Standard/Guidance Document Referenced:

1. Guidance: Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final, 02/22/1999
   Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use, 11/30/2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Victor M. Carrio
RA/QS Compliance Manager
Dade Behring, Inc.
500 GBC Drive
Mailstop 514
Newark, DE 19714-6101

AUG 16 2006

Re: k062152
Trade/Device Name: Creatine Kinase MB Isoenzyme Verifier (DC27)
Regulation Number: 21 CFR§862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: July 26, 2006
Received: July 27, 2006

Dear: Mr. Carrio

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

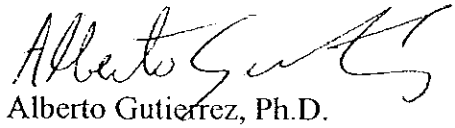
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known): K062152

Device Name:

Creatine Kinase MB Isoenzyme Verifier (DC27)

Indications for Use:

The Creatine Kinase MB Isoenzyme Verifier is an *in vitro* diagnostic product for verification of the Creatine Kinase MB Isoenzyme (CKMB) method on the Dimension® clinical chemistry system and Dimension Vista™ System

Prescription Use __X__ **AND/OR** **Over-the-counter Use** _____
(Per 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of -In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K062152